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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,698	08/07/2002	Mohsen Shahinpoor		9324

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EXAMINER

BERKO, RETFORD O

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/064,698

Applicant(s)

SHAHINPOOR ET AL.

Examiner

Retford Berko

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***DETAILED ACTION***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3, 4, 5, 9, 10-19 are rejected under 35 U.S.C.103(a) as being unpatentable over Wallace et al (US 6,476, 037 filed March 23, 2000) in view of Garfield et al (5, 698, 738) further in view of Green et al (US 5, 358, 714).

The claims are directed toward a method for enhancing hair growth or diminishing hair loss or alopecia, comprising administration of a nitro-vasodilator (minoxidil-like compounds) and a phosphodiesterase -5 (PDE-5) inhibitor (sildenafil citrate) in a dermatologically acceptable solution. The claims are also directed toward the use of nitroglycerine as the NO releasing agent, O-nitroso compounds, nitrites, nitosylated oligo-saccharides and polysaccharides, specific PDE-5 inhibitors and tonicity adjusting agents and antioxidants.

Wallace et al (Patent '037) disclose that L-arginine and type 5 phosphodiesterase inhibitors (sildenafil) have synergistic effect in vasodialative effect (abstract, col 5, lin 45-55, col 21, lin 60-65). According to Wallace, the interaction between sildenafil and nitric oxide donors may have clinical use for amplification of the effects of l-arginine, nitroglycerin or other NO donors in relation to vasodilation (col 22, lin 55-60).

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Patent 037 does not teach the use of nitroglycerine, l-arginine or sildenafil as chemical agents that stimulate hair growth or the use of these agents for inhibiting alopecia; either independently or in combination.

Garfield et al (Patent '738) disclose that nitroprusside, nitroglycerin and other NO donors such as l-arginine have important physiological effects due to the nitrous oxide modulating activity; including ability to improve hair growth (col 5, lin 60-65, col 6, lin 50-60m and col7, lin 45-60; Table 2).

Green et al (Patent '714) is relied upon to provide the linking disclosure—i.e. that minoxidol and its derivatives act as hair growth stimulants (col 7, lin 15 continuing to col 8, lin45-50).

One of ordinary skill in the art would have been motivated to make a composition comprising of two apparently different compound, each independently having ability to stimulate hair growth (e.g. NO donor such as nitroglycerine plus phosphodiesterase inhibitor, such as minoxidol or sildenafil). Because of the synergistic effect of nitroglycerin and sildenafil, as disclosed by Wallace (col21, lin 60-65), one of ordinary skill wouldl expect to obtain a composition that would be synergistically effective in promoting hair growth or inhibit alopecia because each of the ingredients have been known to be independently effective as hair growth stimulants. Therefore the invention as a whole wherein applicant is claiming a method of treating alopecia by administering to a mammal a composition comprising of NO donor (l-arginine, nitroglycerine or nitroprusside) and phosphodiesterase inhibitor (sildenafil or minoxidil) would have been prima facie obvious to one of ordinary skill given the known biological effects of the compounds.

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2. Claims 1, 6, 7, 8, and 20-25 are rejected under 35 U.S.C.103(a) as being unpatentable over Wallace et al (US 6,476, 037 filed March 23, 2000) in view of the combination of Rogers et al (6, 747,008; filed November 27, 2000), Bazzano et al (US 5, 183, 817) and Bazzano et al (US 5, 514, 672).

The claims are directed toward a method for enhancing hair growth or diminishing hair loss or alopecia, comprising administration of a nitro-vasodilator (minoxidil-like compounds) and a phosphodiesterase -5 (PDE-5) inhibitor (sildenafil citrate) in a dermatologically acceptable solution. The are further directed toward the method wherein nitrosylated derivative of captopril is substituted as the NO oxide donor, S-nitrosylated protein or peptide and n-nitrosylated polysaccharide are used for making the dermatological composition. Also, the claims are directed toward the use of antimicrobial agents, oral tablets and pharmaceutical vehicles. Finally, the claims are directed toward veterinary preparations and feeds wherein the composition induces fur growth when the feed is fed to animals.

The disclosures of Wallace et al (Patent 037) were discussed above in parag 1.

Patent '037 does not disclose the use of peptides or captopril, peptides and antioxidants.

Rogers et al (Patent '008) a method for treating alopecia, said method includes the use of minoxidol and compounds such as paptopril, captopril-cysteine and captopril-glutathione (col 2, lin 65; continuing to col 3, lin 20-25 and col 35, lin 1-5). Rogers does not disclose the use of antioxidants.

Bazzano et al (Patent '817) discloses the use of a composition comprising minoxidol and minoxidol-type compounds and anti-oxidant retinoids or tochopherols for stimulating hair

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growth; said composition in formulations such as topical lotions and creams (abstract, col 3, lin 60-65; col 5, lin 15-20; col 18, lin 30; col 20, lin 4-50; col 24, lin 40 and col 29, lin 30-35).

Bazzano et al (Patent '672) is relied upon to provide a disclosure wherein a composition that stimulates hair growth when used topically; said composition comprising of retinoids (abstract, and col 30, lin 40-45). Patent '672 discloses that the hair-stimulating retinoid composition is formulated as a pharmaceutical, cosmetic and veterinary formulations and can be administered orally and in compounds added to animal foods (col 20, lin 60-67). Significantly, Patent '672 discloses that the retinoid compounds cause excellent percutaneous absorption of active compounds on keratinizing cells of the skin and helps overcome a major problem encountered in absorption of active compounds for stimulation of hair growth (col 20, lin 45-50).

One of ordinary skill would have been motivated to prepare pharmaceutical, cosmetic and veterinary compositions comprising of agents shown to stimulate hair growth in both man and animals and add to such compositions tocopherols such as retinoic acid to the formulations. Because of the ability to stimulate percutaneous absorption of active compounds, one of ordinary skill would expect to obtain excellent absorption of the ingredients and thereby increase the rate of hair growth by administering the formulations to patients and pets. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill at the time that it was made.

### **Trademarks**

Claim 1, 14 and 16 contains the trademark/trade name Rogaine<sup>RTM</sup>. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph.

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See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe sildenafil and, accordingly, the identification/description is indefinite.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 703-305-4442. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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